

The Honorable Tana Lin

UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF WASHINGTON

SUSAN FITZL and SAMANTHA HORTON,
on behalf of themselves and a class of all
others similarly situated,

Plaintiffs,

V.

AMAZON.COM, INC.,

Defendant.

No. 2:22-cv-00544-TL

**DEFENDANT AMAZON.COM, INC.'S
MOTION TO DISMISS PLAINTIFFS'
FIRST AMENDED COMPLAINT**

**NOTE ON MOTION CALENDAR:
OCTOBER 21, 2022**

ORAL ARGUMENT REQUESTED

MOTION TO DISMISS PLAINTIFFS' FIRST AMENDED COMPLAINT
CASE NUMBER 2:22-CV-00544-TL

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MOTION TO DISMISS PLAINTIFFS' FIRST AMENDED COMPLAINT - iv
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MOTION TO DISMISS PLAINTIFFS' FIRST AMENDED COMPLAINT - vi
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1 Defendant Amazon.com, Inc. (“Amazon”) moves to dismiss Plaintiffs’ First Amended
 2 Complaint (“FAC”) with prejudice pursuant to Fed. R. Civ. P. 8(a), 9(b), 12(b)(1), and 12(b)(6).

3 **I. PRELIMINARY STATEMENT**

4 Plaintiffs’ FAC challenges the labeling of certain over-the-counter (“OTC”) cold
 5 medicines containing dextromethorphan hydrobromide (“DXM”), a cough suppressant known as
 6 an antitussive. Plaintiffs allege that they purchased OTC medications containing DXM from
 7 Amazon for severe cold and flu symptoms, “took the medicine as directed,” and “became
 8 unexpectedly drowsy.” FAC (Dkt. #31) ¶¶ 8–9. Based on those facts, Plaintiffs assert five state-
 9 law claims, allege that labeling DXM-containing medicines as “non-drowsy” or “daytime” is false
 10 and misleading, and seek an order requiring Amazon to remove those terms from product labels.
 11 *Id.* ¶¶ 32–37. Plaintiffs fail to state plausible claims for relief for several reasons.

12 First, federal law preempts Plaintiffs’ claims. The federal Food and Drug Administration
 13 (“FDA”) strictly regulates the labeling of OTC medicines through a “monograph” process. Over
 14 the course of 15 years, the FDA reviewed the efficacy and safety of antitussives, including DXM,
 15 and found “no data demonstrating that the antitussive ingredient[] … [DXM] … requires a
 16 drowsiness warning.” 48 Fed. Reg. 48,576, 48,589 (Oct. 19, 1983). Accordingly, the FDA’s final
 17 regulation concerning the labeling of OTC antitussives does not require products with DXM to
 18 display a drowsiness warning or disclose drowsiness as a side effect. Nor does it prohibit labeling
 19 OTC products containing DXM as non-drowsy or for daytime use. *See* 21 C.F.R. § 341.74 (titled
 20 “Labeling of antitussive drug products”). To protect the integrity of this regulatory framework,
 21 the federal Food, Drug, and Cosmetic Act (“FDCA”) preempts any state-law claims that purport
 22 to impose requirements “different from,” “in addition to,” or “otherwise not identical with” the
 23 FDA’s final labeling requirements. 21 U.S.C. § 379r(a). Specifically, “§ 379r(a) preempts state
 24 law claims [1] that require additional information or labeling or [2] that prohibit labeling beyond
 25 what is expressly stated in the applicable federal requirements.” *McFall v. Perrigo Co.*, No. 2:20-
 26 cv-07752-FLA, 2021 WL 2327936, at *8 (C.D. Cal. Apr. 15, 2021) (citing cases).

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1 Notwithstanding FDCA section 379r, Plaintiffs seek to prohibit use of the terms “non-
 2 drowsy” and “daytime” on the labels of certain Basic Care OTC medicines as false and misleading
 3 because, according to Plaintiffs, DXM causes drowsiness. *See* FAC ¶¶ 32–37. Plaintiffs assert
 4 that Amazon should have omitted the “non-drowsy” description, changed the label to “less
 5 drowsy,” or disclosed drowsiness as a side effect. *Id.* ¶¶ 32–39. Plaintiffs ignore, however, that
 6 “[w]ith respect to the labeling of OTC drugs, the whole point of section 379r is that it is not up to
 7 private litigants—or judges—to decide what is ‘false or misleading.’ It is up to the FDA.” *Bowling*
 8 *v. Johnson & Johnson*, 65 F. Supp. 3d 371, 377 (S.D.N.Y. 2014). And “[b]ecause the FDA alone
 9 can balance the potentially competing concerns of safety and effectiveness, common law and state
 10 law liability that is also premised on a product’s safety and effectiveness can only upset that
 11 balance.” *Carter v. Novartis Consumer Health, Inc.*, 582 F. Supp. 2d 1271, 1281 (C.D. Cal. 2008).
 12 Section 379r therefore preempts all of Plaintiffs’ claims because, “[i]f successful, this litigation
 13 would do exactly what Congress, in passing section 379r of the FDCA, sought to forbid: using
 14 state law causes of action to bootstrap labeling requirements that are ‘not identical with’ federal
 15 regulation.” *Bowling*, 65 F. Supp. 3d at 376. As recently as last month, the District Court for the
 16 Middle District of Florida followed this clear authority and dismissed virtually identical state-law
 17 claims challenging the labeling of a “non-drowsy” antitussive, holding that they were squarely
 18 preempted. *See Amara v. Publix Supermarkets, Inc.*, No. 8:22-cv-367-VMC-JSS, 2022 WL
 19 3357575, at *4–5 (M.D. Fla. Aug. 15, 2022) (holding § 379r(a) preempted plaintiff’s claims).

20 Second, the FAC’s conclusory allegations that DXM may cause drowsiness and that the
 21 challenged medicines caused Plaintiffs to feel “unexpectedly drowsy” do not support plausible
 22 claims for relief. Plaintiffs allege that they purchased and took the medicines targeting “severe”
 23 cold and flu symptoms. But these conclusory statements are not accompanied by well-pled facts
 24 supporting a conclusion that the medications caused their alleged drowsiness. For good reason:
 25 cold and flu viruses, among many other things, cause fatigue. “[W]ithout some further factual
 26

1 enhancement,” Plaintiffs’ speculative allegations “stop[] short of the line between possibility and
 2 plausibility of entitlement to relief.” *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 557 (2007).

3 Third, Plaintiffs’ claims fail for additional reasons, including that: (1) the breach of
 4 warranty claim is barred by an explicit disclaimer of all warranties and a failure to provide timely
 5 notice; (2) the unjust enrichment claim and other requests for equitable relief fail because Plaintiffs
 6 have an adequate legal remedy; (3) the negligent and intentional misrepresentation claims do not
 7 satisfy Rules 8(a) and 9(b); and (4) Plaintiffs lack Article III standing to pursue injunctive relief.

8 For each of the above reasons, the Court should dismiss Plaintiffs’ claims with prejudice.

9 II. BACKGROUND

10 A. Federal Regulation of Over-the-Counter Drugs

11 The FDA regulates most OTC medications through a monograph process. A monograph
 12 is a set of regulations that describes the conditions under which a category of drugs may be
 13 marketed without a prescription. *See* 21 C.F.R. § 330.1 (titled “General conditions for general
 14 recognition as safe, effective and not misbranded”); *id.* § 330.10 (titled “Procedures for classifying
 15 OTC drugs as generally recognized as safe and effective and not misbranded, and for establishing
 16 monographs”). A monograph is “like a recipe” for each category of OTC drugs: it “sets out the
 17 FDA-approved active ingredients for a given therapeutic class of OTC drugs” and specifies
 18 acceptable doses, formulations, and labeling for those drugs. *Nat. Res. Def. Council, Inc. v. U.S.
 19 Food & Drug Admin.*, 710 F.3d 71, 75 (2d Cir. 2013) (describing the monograph process). An
 20 OTC drug that complies with its monograph “is generally recognized as safe and effective and is
 21 not misbranded.” 21 C.F.R. § 330.1.

22 The FDA’s monograph process is rigorous. A monograph is developed only after the FDA
 23 has appointed an advisory panel of independent experts, which “review[s] all available data” and
 24 reports its “conclusions and recommendations” to the FDA “with respect to the safety and
 25 effectiveness of the drugs.” *Id.* § 330.10(a). Based on the panel’s recommendations, the FDA
 26 publishes a proposed monograph for public comment, followed by a later “tentative final

1 monograph” (“TFM”) for further public comment. *Id.* § 310.10(a)(7). “After reviewing [any]
 2 objections, the entire administrative record including all new data and information and comments,
 3 and considering the arguments made at any oral hearing,” the FDA publishes a final monograph
 4 “establishing conditions under which a category of OTC drugs … or specific OTC drugs are
 5 generally recognized as safe and effective and not misbranded.” *Id.* § 310.10(a)(9).

6 **B. Federal Labeling Requirements for Medicines Containing DXM**

7 The FDA began the monograph process for OTC cough medications in 1972. *See* 41 Fed.
 8 Reg. 38,312, 38,314 (Sept. 9, 1976). After a panel of experts studied the safety and efficacy of the
 9 medications, and after multiple rounds of public comment, the FDA published a TFM for OTC
 10 antitussives in 1983 (48 Fed. Reg. 48,576 (Oct. 19, 1983)) and a final monograph in 1987 (52 Fed.
 11 Reg. 30,042, 30,055–56 (Aug. 12, 1987) (codified at 21 C.F.R. § 341.74)). *See Carter*, 582 F.
 12 Supp. 2d at 1275–76 (C.D. Cal. 2008) (describing OTC antitussive monograph process).

13 The final monograph that emerged from this 15-year process has comprehensive labeling
 14 requirements for products containing DXM. It regulates the indication statements, required
 15 warnings, and dosage directions that must appear on the label. *See* 21 C.F.R. § 341.74 (b)(3)(vi)–
 16 (vii), (c)(4)(v)–(vi), (d)(1)(iii) (titled “Labeling of antitussive drugs”). Importantly, the monograph
 17 neither requires a warning that drowsiness is a side effect of DXM, nor prohibits the labeling of a
 18 product containing DXM as “non-drowsy” or “daytime.” The FDA arrived at these conclusions
 19 after affirmatively considering the relationship between DXM and drowsiness and documenting
 20 in the TFM that it was “*not aware of data demonstrating that* the antitussive ingredient[] … [DXM]
 21 … *require[s] a drowsiness warning.*” 48 Fed. Reg. at 48,589 (emphasis added).

22 By contrast, the FDA requires that other OTC cough medications expressly warn of
 23 potential drowsiness. These warnings take two forms—that a medication “may cause drowsiness”
 24 or that it “may cause marked drowsiness.” 21 C.F.R. §§ 341.72(c)(3) (requiring “drowsiness”
 25 warning for several antihistamines); 341.72(c)(4) (requiring “marked drowsiness” warning for
 26 products containing diphenhydramine or doxylamine); 341.85(c)(4) (requiring “marked

1 drowsiness” warning when an antihistamine is combined with an oral antitussive). Tellingly, the
 2 FDA did not require any such drowsiness disclosure for products containing DXM. *Id.*
 3 § 341.74(c)(4)(i)–(vi) (listing warnings actually required for certain antitussives).

4 **C. Plaintiffs’ Allegations**

5 Plaintiffs purchased medicines for severe cold and flu symptoms. Ms. Fitzl alleges she
 6 purchased a “Basic Care Vapor Ice Daytime and Nighttime *Severe* Cold and Flu combo pack,”
 7 and Ms. Horton alleges she purchased a “Basic Care Daytime *Severe* and Nighttime *Severe* Cold
 8 and Flu combo pack.” FAC ¶¶ 8–9 (emphasis added). Both allegedly “took the medication as
 9 directed” and, at some point thereafter, “became unexpectedly drowsy.” *Id.*

10 Conspicuously absent from the FAC are any fact-based allegations that plausibly connect
 11 the medications (or DXM) to Plaintiffs’ alleged drowsiness. In fact, Plaintiffs offer no meaningful
 12 detail about their particular circumstances, stating only that they were “not on any other medication
 13 that would have caused … drowsiness.” *Id.* Otherwise, Plaintiffs rely on the unsupported and
 14 self-serving statement that “there was no other potential cause for [their] drowsiness.” *Id.* That
 15 conclusory allegation, however, is belied by the FAC itself, which turns on Plaintiffs’ purchase of
 16 medicine designed to treat “severe” cold and flu symptoms. Ultimately, the FAC alleges no facts
 17 from which one can reasonably infer that the medicines, rather than Plaintiffs’ preexisting illnesses
 18 or any of the other reasons one becomes tired, caused their alleged drowsiness.

19 Instead, Plaintiffs allege that the medicines contain DXM, that the internet suggests that
 20 drowsiness can be a side effect of DXM, and that, therefore, “non-drowsy” and “daytime” labels
 21 are false and misleading. Plaintiffs acknowledge the scope and breadth of the FDA regulations
 22 and concede that the FDA does “not require products with [DXM] to include an affirmative
 23 ‘drowsiness’ warning” (*id.* ¶¶ 32 n.11, 37), but they simultaneously (and incorrectly) contend that
 24 the FDA regulations prohibit “voluntary” descriptors such as “non-drowsy.” *Id.* ¶¶ 32–37.

25 Plaintiffs assert claims for: (1) breach of express warranty; (2) violation of the Washington
 26 Consumer Protection Act (“WCPA”), Wash. Rev. Code §§ 19.86, *et seq.*; (3) unjust enrichment;

1 (4) negligent misrepresentation; and (5) intentional misrepresentation. Plaintiffs allege only
 2 economic harm, seeking as damages the full amount they paid for the products or an unspecified
 3 amount they purportedly would have saved had the labeling been different. *Id.* ¶¶ 42–45. Plaintiffs
 4 also seek equitable relief (restitution) and a vague, undefined injunction. *See id.* pp. 20–21.

5 III. LEGAL STANDARD

6 “[T]o satisfy Rule 8(a)(2) a complaint must contain sufficient factual content ‘to state a
 7 claim to relief that is plausible on its face.’” *Landers v. Quality Commc’ns, Inc.*, 771 F.3d 638,
 8 641 (9th Cir. 2015) (quoting *Twombly*, 550 U.S. at 570). Plausibility requires “more than a sheer
 9 possibility that a defendant has acted unlawfully.” *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009).
 10 “Where a complaint pleads facts that are ‘merely consistent with’ a defendant’s liability, it ‘stops
 11 short of the line between possibility and plausibility of ‘entitlement to relief.’” *Id.* (quoting
 12 *Twombly*, 550 U.S. at 557). Plaintiffs must allege *facts*—not mere “labels and conclusions[,]”
 13 “formulaic recitation[s] of the elements of a cause of action[,]” or “naked assertion[s] devoid of
 14 further factual enhancement”—to elevate their claims from merely possible, to plausible. *Id.*

15 Courts do not apply this analysis in a vacuum. Instead, “determining whether a complaint
 16 states a plausible claim is context specific, requiring the reviewing court to draw on its experience
 17 and common sense.” *Iqbal*, 556 U.S. at 663–64; *see Grigsby v. Valve Corp.*, No. C12-0553JLR,
 18 2012 WL 5993755, at *4 (W.D. Wash. Nov. 14, 2012) (recognizing that “context matters” and
 19 granting Rule 12(b)(6) motion). Plaintiffs must also satisfy Rule 9(b) and plead their claims—all
 20 of which sound in fraud—with particularity. *See Vess v. Ciba-Geigy Corp. USA*, 317 F.3d 1097,
 21 1103–04 (9th Cir. 2003) (claims “grounded in fraud” must satisfy Rule 9(b)).

22 IV. ARGUMENT

23 A. The FDCA Preempts Plaintiffs’ Claims

24 1. *The FDCA broadly preempts state law claims challenging the labeling 25 of OTC antitussives*

26 Congress enacted Section 379r of the FDCA to bring national uniformity to the labeling of

1 OTC drugs. *See* 21 U.S.C. § 379r (titled “National uniformity for nonprescription drugs”).
 2 Section 379r thus contains an express preemption clause, prohibiting states from establishing “any
 3 requirement … that is different from or in addition to, or that is otherwise not identical with”
 4 federal law. *Id.* § 379r(a). This preemption is sweeping, reaching any state-law cause of action
 5 that purports to impose a labeling requirement or prohibition that is different from, in addition to,
 6 or not identical with federal law on the subject. *See Reigel v. Medtronic, Inc.*, 552 U.S. 312, 324–
 7 25 (2008) (interpreting a similar preemption provision and finding that “reference to a State’s
 8 ‘requirements’ includes its common-law duties”); *Carter*, 582 F. Supp. 2d at 1282 (“virtually any
 9 state requirement that relates to the regulation of nonprescription drugs can be preempted,
 10 regardless of the common law theory under which it is brought”).

11 “In the context of OTC drugs,” courts have found FDCA preemption applies **both** “when
 12 a state law prohibits labeling that is permitted under federal law” **and** “when a state law prohibits
 13 labeling that is *not prohibited* under federal law[.]” *Wiltz v. Chattem, Inc.*, No. CV 15-1352-R,
 14 2015 WL 3862368, at *1 (C.D. Cal. May 8, 2015); *see also Bowling*, 65 F. Supp. 3d at 375 (“The
 15 standard … is not whether a state law actively undermines federal law. It is whether the state law
 16 diverges from federal law *at all*.”). Put another way, “§ 379r(a) preempts state law claims that
 17 require additional information or labeling or that prohibit[] labeling beyond what is expressly
 18 stated in the applicable federal requirements.” *McFall*, 2021 WL 2327936, at *8; *see also Kanter*
 19 *v. Warner-Lambert Co.*, 99 Cal. App. 4th 780, 795 (2002) (“[W]hen a claim is premised ultimately
 20 on the inadequacy of the product label, it is preempted.”).

21 Final FDA monographs have preemptive effect under the FDCA. *See Youngblood v. CVS*
 22 *Pharmacy*, No. 2:20-cv-06251-MCS-MRW, 2021 WL 3700256, at *2–3 (C.D. Cal. Aug. 17, 2021)
 23 (mislabeling claims preempted by requirements in FDA monograph); *Kanter*, 99 Cal. App. 4th at
 24 795 (discussing the preemptive effects of monographs). Preemption is especially appropriate in
 25 the monograph context because, “[w]ith respect to the labeling of OTC drugs, the whole point of
 26 section 379r is that it is not up to private litigants—or judges—to decide what is ‘false or

1 misleading.’ It is up to the FDA.” *Bowling*, 65 F. Supp. 3d at 377. Accordingly, where a final
 2 monograph regulates the labeling of an OTC drug, the FDCA precludes any state requirements or
 3 prohibitions, through common law claims or otherwise, “unless they are *identical* to federal
 4 standards.” *Id.* at 375 (internal quotation marks omitted); *see also id.* at 377 (to defeat preemption
 5 “plaintiffs would need to plead facts suggesting that the FDA has affirmatively *prohibited* the
 6 label”); *McFall*, 2021 WL 2327936, at *8 (preemption operates if “the packaging elements
 7 Plaintiffs have identified as false or misleading … are required, or *not prohibited* under the statutes,
 8 regulations, and monographs that apply to OTC … products.” (emphasis added)).

9 2. *Plaintiffs’ state law claims targeting non-drowsy labeling are preempted*

10 Plaintiffs’ state-law claims seek to require Amazon to remove the terms “non-drowsy” and
 11 “daytime” from the labels of OTC antitussives containing DXM, on the grounds that those terms
 12 are false and misleading because DXM “cause[s] drowsiness” or “drowsiness is a known side
 13 effect” of DXM. FAC ¶¶ 34–37. The FDA’s antitussive monograph, however, does not prohibit
 14 the use of the terms “non-drowsy” or “daytime.” Instead, the FDA considered the relationship
 15 between DXM and drowsiness and found no data to support a drowsiness warning. *See* 48 Fed.
 16 Reg. at 48,589. Plaintiffs’ claims, therefore, seek to *change* the “non-drowsy” and “daytime”
 17 wording on the products’ labels and *codify* a new labeling prohibition that is different from, in
 18 addition to, and not identical to governing FDA regulations.

19 If Plaintiffs are permitted to pursue such claims, they would be impermissibly using “state
 20 law causes of action to bootstrap labeling requirements that are ‘not identical with’ federal
 21 regulation.” *Bowling*, 65 F. Supp. 3d at 376. The FDCA preempts and prohibits this result. *See*
 22 *Harris v. Topco Assocs., LLC*, 538 F. Supp. 3d 826, 833 (N.D. Ill. 2021) (plaintiff’s “claims are
 23 preempted because she seeks to impose additional obligations on [defendant] not imposed by the
 24 [monograph]”); *Youngblood*, 2021 WL 3700256, at *3 (dismissing claims as preempted where
 25 they “seek to do more than bring the packaging at issue in line with federal requirements”); *Gisvold*
 26 *v. Merck & Co., Inc.*, 62 F. Supp. 3d 1198, 1203 (S.D. Cal. 2014) (“Because the proposed

1 disclaimer plainly adds to and is not identical with the FDA’s requirements, Plaintiff’s action is
 2 expressly pre-empted”); *Kanter*, 99 Cal. App. 4th at 797 (“Because all of plaintiffs’ state law
 3 causes of action … are also based ultimately on the assertion that the labels on those products are
 4 no longer accurate or adequate, they … cannot escape preemption.”).

5 Plaintiffs attempt to avoid preemption by arguing that the FDA monograph does not
 6 expressly *endorse* use of the terms “non-drowsy” or “daytime” for products with DXM. *See* FAC
 7 ¶¶ 34–35. This is a non-starter. As a practical matter, the FDA cannot list out every word that *is*
 8 permissible for every label for every type of OTC product. That is precisely why the FDCA
 9 prohibits not only state law claims that purport to impose requirements “different from” the FDA’s
 10 labeling requirements, but also any claims that seek to impose requirements or restrictions “in
 11 addition to” or “otherwise not identical with” those labeling requirements. 21 U.S.C. § 379r(a).
 12 But, more importantly, courts have rejected this argument, holding that state law cannot prohibit
 13 “labeling that is *not prohibited* under federal law.” *Wiltz*, 2015 WL 3862368, at *1; *see also*
 14 *McFall*, 2021 WL 2327936, at *8 (same). This holds particularly true where, as here, the FDA
 15 considered whether DXM causes drowsiness and declined to: (i) require a drowsiness warning; or
 16 (ii) restrict the type of language, *i.e.*, “non-drowsy” or “daytime,” that Plaintiffs challenge.

17 The recent decision of the Middle District of Florida in *Amara v. Publix Supermarkets, Inc.*—in which the court dismissed virtually identical state-law claims as preempted by the
 18 FDCA—is directly on point. *See* 2022 WL 3357575, at *4–5. The plaintiff in *Amara*, like
 19 Plaintiffs here, alleged that a “non-drowsy” label on an OTC antitussive containing DXM was
 20 misleading because DXM “is well known for causing drowsiness.” *Id.* at *1. The plaintiff asserted
 21 various state-law claims and the defendant moved to dismiss on the grounds that Section 379r(a)
 22 of the FDCA preempts such claims. *Id.* at *1, *4–5. The court agreed, explaining that state-law
 23 claims are preempted if “federal requirements address the subject matter being challenged” and
 24 plaintiff’s claims clearly sought to impose requirements not identical to the federal standards. *Id.*
 25 at *5 (citing *Bowling*, 65 F. Supp. 3d 371, 376 (S.D.N.Y. 2014)). The court acknowledged that

1 the FDA monograph “established requirements applicable to” antitussives containing DXM and
 2 that the monograph included guidance about “the potential drowsiness side effects of certain
 3 antitussive medications.” *Id.* The court thus found that “all of [plaintiff’s] state-law claims [were]
 4 preempted by the FDCA because they seek to impose a labeling requirement that is ‘different from
 5 or in addition to, or that is otherwise not identical with, a requirement’ for OTC drugs in the
 6 applicable regulations.” *Id.* at *5 (quoting 21 U.S.C. § 379r(a)).

7 The *Amara* court expressly rejected the primary argument Plaintiffs are making here to try
 8 to avoid preemption. There, like here, the plaintiff attempted to distinguish between claims
 9 “seeking to add a drowsiness warning[,]” which he conceded would be preempted, and claims
 10 seeking only the “removal” of an allegedly false or misleading term, which he argued should not
 11 be preempted. *Id.* at *4; *see also* FAC ¶¶ 32 n.11, 37. In the *Amara* plaintiff’s view, because the
 12 monograph did not “require[] or approve[]” the term “non-drowsy” and the defendant “voluntarily
 13 added the affirmative misrepresentation of ‘non-drowsy’ to the [p]roduct labeling, requiring it to
 14 remove this statement would impose no additional disclosure requirements.” *Id.* The *Amara* court
 15 rejected this argument as “a distinction without a difference,” finding that the plaintiff’s claims
 16 were preempted because, if successful, they would impose liability “for labeling the product ‘non-
 17 drowsy’ when such labeling complies with the FDA’s [m]onograph.” *Id.* at *4–5. This Court
 18 should follow *Amara*—which addressed virtually identical claims, turned on the same preemption
 19 provisions and monograph, and rejected the very argument that Plaintiffs raise—and find
 20 Plaintiffs’ claims preempted.

21 Various other cases offer additional insight. In *Carter v. Novartis*, the Central District of
 22 California dismissed state law claims challenging the labeling on certain OTC cough medicines as
 23 safe for children under six. 582 F. Supp. 2d at 1276–77, 1284–85. During the monograph process
 24 for the medicines at issue, and after considering relevant evidence, the FDA only prohibited the
 25 use of the medicines to treat children under two. *Id.* at 1276–77. Citing “various studies, articles
 26 from the New York Times, and two recent clinical studies,” the plaintiffs nonetheless brought

1 fraud and warranty claims alleging that the defendants “knew or should have known” the products
 2 were dangerous to other children and should not have marketed them as “safe and effective for
 3 children under six.” *Id.* The court found plaintiffs’ claims preempted because the marketing
 4 statements were “based entirely upon FDA-approved labeling and advertising,” which
 5 “explain[ed] the conditions under which the FDA … determined that OTC cough and cold
 6 medicine will be safe and effective.” *Id.* at 1284–85. That was so because, while the FDA
 7 considered potential restrictions related to children under six, it ultimately did not prohibit labels
 8 from saying they were “safe and effective for children under six.” *Id.*

9 The California Court of Appeals reached a similar conclusion in *Eckler v. Neutrogena*
 10 Corp., 238 Cal. App. 4th 433, 456–57 (2015). In that case, the court held that a plaintiff could not
 11 pursue claims that it was misleading to label sunscreen as “sunblock,” “waterproof,” or
 12 “sweatproof,” when the FDA had considered but not prohibited the use of those terms. *Id.*

13 Additionally, in *Bowling v. Johnson & Johnson*, the Southern District of New York
 14 rejected the plaintiffs’ attempt to force the maker of Listerine to remove the statement “restores
 15 enamel” from its mouthwashes. 65 F. Supp. 3d at 373. There, the plaintiffs claimed the statement
 16 was false because, they alleged, enamel loss was permanent and no mouthwash could restore it.
 17 *Id.* The court found the claims preempted, however, because the FDA had issued regulations
 18 concerning appropriate labeling for mouthwash and did not prohibit use of the language “restores
 19 enamel.” *Id.* at 376. The court reasoned that “[t]his case might be different if the FDA had issued
 20 no guidance as to dental hygiene products,” but that, “[a]s it stands, … the FDA has issued a
 21 monograph directly on point but declined, in spite of that, to indicate … that ‘Restores Enamel’ is
 22 misleading.” *Id.*; see also *Wiltz*, 2015 WL 3862368, at *2 (same).

23 Finally, in *McFall v. Perrigo Co.*, the Central District of California reiterated the broad
 24 preemptive scope of § 379r(a), which not only preempts claims that “require additional
 25 information or labeling” (i.e., like adding a drowsiness warning), but also claims that “prohibit[]
 26 labeling beyond what is expressly stated in the applicable federal regulation” (i.e., like prohibiting

1 the terms “non-drowsy” or “daytime”). 2021 WL 2327936, at *8 (claims preempted if the
 2 challenged labeling is “not prohibited under [applicable] statutes, regulations, and monographs”).
 3 Although the *McFall* court found the claims at issue not preempted, it did so because the TFM
 4 required the use of the term “children” and appeared to prohibit the use of the term “infant” (which
 5 was used on the challenged labels). *Id.* at *9–10.

6 Importantly, the above-described cases each turned on state-law claims—like those
 7 asserted here—that sought to impose labeling requirements and restrictions on subject matters that
 8 the FDA had previously considered and regulated. That sets those cases, and this case, apart from
 9 cases like *Astiana v. Hain Celestial Group, Inc.*, 783 F.3d 753 (9th Cir. 2015), which turned instead
 10 on labeling challenges concerning subject matters *never* considered by the FDA and *not* addressed
 11 by any applicable federal regulations. *Compare Astiana*, 783 F.3d at 758–59 (holding that claims
 12 targeting the labeling of cosmetics as “natural” were not preempted because “the FDA ha[d] never
 13 issued regulations regarding the use of ‘natural’ on cosmetics labels”), *with Durnford v.*
 14 *MusclePharm Corp.*, 907 F.3d 595, 602 (9th Cir. 2018) (distinguishing *Astiana* because “[n]o
 15 statute or regulation governed the use of ‘natural’ on cosmetics labels” (internal quotation marks
 16 omitted)). In other words, *Astiana* stands for the unremarkable—and inapposite—proposition that
 17 preemption does *not* apply when “the FDA says nothing about the subject matter” of a plaintiff’s
 18 claims. *Bimont v. Unilever U.S., Inc.*, No. 14-CV-7749 (JPO), 2015 WL 5256988, at *3–5
 19 (S.D.N.Y. Sept. 9, 2015) (distinguishing *Astiana*).

20 Unfortunately, litigants and courts alike have misread and misapplied *Astiana*. The Central
 21 District of California in *Lemus v. Rite Aid Corp.*, for example, recently rejected preemption of
 22 “non-drowsy” labeling claims on the mistaken ground that *Astiana* held that preemption could
 23 only apply if the FDA had expressly authorized use of the term “non-drowsy” in its final
 24 regulations. *See* No. 22-cv-00253, 2022 WL 2721385, at *2–3 (C.D. Cal. July 7, 2022).
 25 Respectfully, the *Lemus* court’s treatment of *Astiana* is incorrect. *Lemus* conspicuously fails to
 26 acknowledge, or analyze, that the FDA expressly considered the connection, if any, between DXM

1 and drowsiness and the labeling parameters for medicines containing DXM. In other words,
 2 *Lemus* mistakenly ignores that the “non-drowsy” labeling claims before it fell into the “considered
 3 and addressed” category like those in *Amara*, *Carter*, *Eckler*, and *Bowling*—which are
 4 preempted—and not into the “never been addressed” category of claims like those in *Astiana*.

5 Ultimately, the FDA has set forth specific requirements for the labeling of OTC medicines
 6 containing DXM. Through their claims, Plaintiffs seek to graft additional, different, and non-
 7 identical prohibitions onto the FDA’s requirements. As such, “[i]f Plaintiffs were permitted to
 8 move forward with their claims, they would be using state law to impose labeling requirements on
 9 top of those already mandated in the FDCA and the regulations promulgated thereunder [which]
 10 ... is exactly what the FDCA does not permit.” *Critchero v. L’Oreal USA, Inc.*, 959 F.3d 31, 36
 11 (2d Cir. 2020); *see also Turek v. General Mills, Inc.*, 662 F.3d 423, 427 (7th Cir. 2011) (“The
 12 disclaimers that the plaintiff wants added ... are not identical to the labeling requirements imposed
 13 on such products by federal law, and so they are barred.”). Plaintiffs’ claims are therefore
 14 preempted, and the Court should dismiss the FAC in its entirety and with prejudice.

15 **B. Plaintiffs Do Not Plausibly Allege that the Labels are False or Misleading**

16 Plaintiffs’ claims turn on the conclusory allegation that DXM causes or may cause
 17 drowsiness. From there, Plaintiffs contend that the labeling is false, deceptive, and misleading
 18 because it uses the terms “non-drowsy” and “daytime” and “do[e]s not disclose anywhere on the
 19 packaging that [the medicines] ... do or can cause drowsiness, or that drowsiness is a side effect.”
 20 FAC ¶¶ 32–33. These allegations are insufficient under Rules 8(a) and 9(b) to sustain a plausible
 21 claim that the medicines cause or may cause drowsiness.

22 ***I. Plaintiffs fail to plausibly allege that DXM causes drowsiness***

23 To support the contention that DXM causes drowsiness, Plaintiffs primarily rely on
 24 materials found on the internet. Those sources, however, do not support a plausible inference that
 25 drowsiness is, in fact, a “well-documented side effect” of DXM. FAC ¶ 24.
 26

1 First, Plaintiffs misleadingly cite two papers for the proposition that “sedation is a well-
 2 known adverse event of [DXM].” *Id.* ¶ 30. In one, the very first paragraph belies Plaintiffs’
 3 allegation, stating that, as an antitussive, “DXM has strong safety and efficacy profiles *with no*
 4 *sedative* or addictive properties *at the recommended doses.*” A. Siu & R. Drachtman,
 5 *Dextromethorphan: A Review of N-methyl-d-aspartate Receptor Antagonist in the Management of*
 6 *Pain*, 13 CNS Drug Reviews 1, 96–106, 96 (2007) (emphasis added) (Ex. A to the Declaration of
 7 Ruby Nagamine (“Nagamine Decl.”)).¹ It is only where the study addresses “overdoses” of DXM
 8 or its use “at higher doses” that it notes adverse effects that may include drowsiness. *Id.* at 99,
 9 102. The other study is equally unhelpful to Plaintiffs’ FAC, as it acknowledges that “a sedative
 10 effect … was … little reported” when DXM was used to treat pain, and that the pain relieving
 11 “effect of [DXM] is *not accompanied by a sedative effect.*” E. Martin, *et al.*, *Dextromethorphan*
 12 *Analgesia in a Human Experimental Model of Hyperalgesia*, 131 Anesthesiology 2, 365–66 (Aug.
 13 2019) (emphasis added) (Ex. B to Nagamine Decl.). Both papers address the potential use of DXM
 14 to relieve pain at dosages higher than those recommended for antitussive purposes, and neither
 15 purports to establish a causal relationship between recommended dosages of DXM and drowsiness.
 16 See *Manuel v. Pepsi-Cola Co.*, 763 F. App’x 108, 109 (2d Cir. 2019) (finding no plausible
 17 inference that the term “diet” was false, inaccurate, or misleading where “[n]one of the studies
 18 purport to establish a causal relationship … to a degree that is sufficiently strong”).

19 Second, Plaintiffs point to a 1997 study that, they contend, confirms drowsiness is a
 20 common side effect of DXM. See FAC ¶ 29. This study compared the efficacy of DXM with
 21 another cough suppressant, levodropopizine, and was co-authored by the pharmaceutical
 22 company that produced levodropopizine. See E. Catena and L. Daffonchio, *Efficacy and*
 23 *Tolerability of Levodropopizine in Adult Patients with Non-productive Cough. Comparison with*
 24 *Dextromethorphan*, 10 Pulmonary Pharmacology & Therapeutics 89–96, 89 (1997) (Ex. C. to

25 ¹ The Court may consider the studies, papers, websites, and other materials expressly referenced in the FAC. See
 26 *Swartz v. KPMG LLP*, 476 F.3d 756, 763 (9th Cir. 2007) (“[A] court may consider a writing referenced in a complaint
 but not explicitly incorporated therein if the complaint relies on the document and its authenticity is unquestioned.”).

1 Nagamine Decl.). Contrary to Plaintiffs' allegations, the authors actually concluded that
 2 drowsiness "was reported for a low percentage of patients with both drugs[.]" *Id.* at 89 (emphasis
 3 added). The study also lacked a placebo group, which the authors recognized as a potential
 4 limitation. *See id.* at 95 ("Lack of a placebo control group might represent a limitation of this
 5 trial"). Moreover, the study confirmed that some patients reported drowsiness even before taking
 6 DXM, confirming that drowsiness could be attributable to other causes. *See id.* at 91. Given its
 7 limitations and ultimate conclusion, and even if a single study could be sufficient to satisfy Rules
 8(a) and 9(b), this study does not support a causal connection between DXM and drowsiness. *See*
 9 *Manuel*, 763 F. App'x at 109 (affirming dismissal of false advertising claims where studies relied
 10 on did not establish a "sufficiently strong" causal relationship).

11 Third, Plaintiffs mischaracterize two online FAQ pages, which describe drowsiness as a
 12 potential symptom of an *overdose* of DXM. *See Mayo Clinic, Drugs and Supplements:*
Dextromethorphan (Oral Route), 7–8 (listing "drowsiness" as a "[s]ymptom[] of overdose" and
 14 "drowsiness (mild)" as "[l]ess common or rare") (Ex. D to Nagamine Decl.); Nat'l Institutes of
 15 Health/Nat'l Library of Med., *Dextromethorphan: Medline Plus Drug Information*, 4 (listing
 16 "drowsiness" as a potential "[s]ympton[] of overdose") (Ex. E to Nagamine Decl.). Potential
 17 overdose symptoms have no bearing on Plaintiffs' allegation that proper use of the medicines at
 18 the recommended dosage cause drowsiness. The National Institutes of Health webpage lists
 19 "drowsiness" (among seven other reactions) under the heading "Tell your doctor if any of these
 20 symptoms are severe or do not go away." *Id.* at 3. To the extent that webpage can be read to
 21 suggest drowsiness is a possible side effect of DXM outside the overdose context, it does not
 22 provide any explanation, data, or support for that suggestion. It thus lacks sufficient detail to
 23 "cross the threshold from allegations of correlation to causation." *Becerra v. Dr Pepper/Seven*
 24 *UP, Inc.*, No. 17-cv-05921-WHO, 2018 WL 3995832, at *6, *8–9 (N.D. Cal. Aug. 21, 2018)
 25 (finding studies cited by plaintiff did not "supply the plausibility of a causal link between Diet Dr
 26 Pepper and weight gain"), *aff'd*, 945 F.3d 1225 (9th Cir. 2019).

MOTION TO DISMISS PLAINTIFFS' FIRST AMENDED COMPLAINT - 15
 CASE NUMBER 2:22-CV-00544-TL

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1 Fourth, Plaintiffs point to two documents, identified as “safety data sheets,” from other
 2 entities, both of which are irrelevant to the medicines in this case. *See* FAC ¶¶ 27–28. One
 3 document addresses a Robitussin product and the other concerns a commercially available, raw
 4 form of DXM. Pfizer, *Safety Data Sheet for Robitussin Cough and Chest Congestion DM*, dated
 5 Feb. 23, 2018, at 6 (emphasis added) (Ex. F to Nagamine Decl.); Santa Cruz Biotechnology, Inc.,
 6 *Dextromethorphan Hydrobromide: Material Safety Data Sheet* (Ex. G to Nagamine Decl.).
 7 Neither document concerns the medicines at issue here. *See Becerra v. Dr Pepper/Seven Up, Inc.*,
 8 945 F.3d 1225, 1230 (9th Cir. 2019) (affirming dismissal of claims where cited advertisements
 9 were “irrelevant to [plaintiff’s] claims”). Importantly, safety data sheets are required by OSHA,
 10 not the FDA, and do not apply to drugs packaged for use by consumers. *See* 29 C.F.R.
 11 § 1910.1200(b)(5)(iii) (exempting drugs subject to FDCA labeling requirements).

12 Finally, Plaintiffs take certain Federal Aviation Administration (“FAA”) guidelines out of
 13 context, suggesting they show that DXM-containing medications cause drowsiness. The FAA
 14 guidelines, however, appear primarily focused on antihistamines or combination products
 15 containing antihistamines. They state that “[m]ost cough medications are safe for flight,” but
 16 caution pilots to avoid “combination products with sedating antihistamines.” FAA, *What Over-*
 17 *the-Counter (OTC) medications can I take and still be safe to fly?*, 3 (Nov. 13, 2019) (Ex. H to
 18 Nagamine Decl.). That guidance comports with FDA rules stating that products containing a
 19 combination of antitussives and antihistamines must disclose that they “may cause marked
 20 drowsiness.” 21 C.F.R. § 341.85(c)(4). But DXM is not an antihistamine, and none of the
 21 medicines Plaintiffs challenge contain antihistamines.

22 **2. Plaintiffs fail to allege that the medicines as a whole cause drowsiness**

23 Plaintiffs also fail to plausibly allege that the challenged medicines as a whole—which
 24 combine DXM with other active ingredients—cause drowsiness. Courts have rejected attempts to
 25 work around the pleading requirements by focusing on one ingredient and ignoring the product as
 26 a whole. *See In re GNC Corp.*, 789 F.3d 505, 510–11, 516 (4th Cir. 2015) (dismissing deceptive

1 marketing claims because “Plaintiffs failed to allege that *all* of the purportedly active ingredients
 2 in each product are ineffective” and thus did not “adequately plead falsity of the representations
 3 regarding the products as a whole.”); *Toback v. GNC Holdings, Inc.*, No. 13-80526-CIV, 2013 WL
 4 5206103, at *5 (S.D. Fla. 2013) (allegations regarding the inefficacy of two ingredients do not
 5 plausibly suggest that the product “*as a whole* does not function as advertised” (emphasis added));
 6 *Eckler v. Wal-Mart Stores, Inc.*, No. 12-cv-727-LAB-MDD, 2012 WL 5382218, at *6 (S.D. Cal.
 7 Nov. 1, 2012) (dismissing false advertising claim where “none of these studies actually involved
 8 Equate” and “it is the overall formulation that’s behind the representation”).

9 Without any plausible and specific allegations that DXM alone—or any of the medicines
 10 as a whole—cause drowsiness, the FAC fails to state a claim for relief and should be dismissed.
 11 See *Aloudi v. Intramedic Research Grp., LLC*, 729 F. App’x 514, 516 (9th Cir. 2017) (affirming
 12 dismissal where plaintiff’s allegations did not involve scientific testing of the challenged product);
 13 see also *Excevarria v. Dr Pepper Snapple Grp., Inc.*, 764 F. App’x 108, 109–10 (2d Cir. 2019)
 14 (affirming dismissal where “[n]one of the studies cited” supported mislabeling claims); *Kardovich*
 15 v. *Pfizer, Inc.*, 97 F. Supp. 3d 131, 141 (E.D.N.Y. 2015) (dismissing deception claims because
 16 cited studies did not raise a plausible inference that the label was false).

17 **3. Plaintiffs fail to plausibly allege that the medicines caused their alleged
 18 drowsiness**

19 Plaintiffs also fail to plausibly connect their own alleged drowsiness to the medicines. The
 20 FAC states only that Plaintiffs were “not on any other medication that would have caused ...
 21 drowsiness” and claims, in conclusory fashion, that “there was no other potential cause for [their]
 22 drowsiness.” FAC ¶¶ 8–9. From there, Plaintiffs ask the Court to assume that their drowsiness,
 23 coming sometime after they took the medicine (they do not say how long), must have been
 24 attributable to DXM, rather than to one of the many other possible causes for drowsiness (e.g.,
 25 large meals, pre-existing conditions, sickness, long hours, or a lack of sleep). This is insufficient.

26 When determining whether the FAC states a plausible claim, “context matters” and the

1 Court must “draw on its experience and common sense.” *Iqbal*, 556 U.S. at 663–64. Here,
 2 Plaintiffs presumably purchased the medicines to treat severe cold or flu symptoms that they were
 3 experiencing at the time. Drawing on common sense, those symptoms could be, and likely were,
 4 a contributing factor to any drowsiness Plaintiffs may have experienced. Without concrete factual
 5 allegations plausibly tying Plaintiffs’ drowsiness to the medicines, the FAC stops short of the line
 6 between mere possibility and plausibility. *See Aloudi*, 729 F. App’x at 517 (rejecting anecdotal
 7 allegations of plaintiffs’ failure to lose weight as not plausibly supporting claims that weight-loss
 8 based marketing was false); *Toback*, 2013 WL 5206103, at *6 (rejecting plaintiff’s allegations that
 9 joint health products “did not repair his cartilage” and thus “did not function as advertised”).

10 C. **Plaintiffs’ Claims Fail for Separate and Independent Reasons**

11 I. **Plaintiffs’ breach of express warranty claim is legally barred**

12 Plaintiffs’ breach of warranty claim fails for two additional reasons.

13 First, Amazon unequivocally disclaimed all express and implied warranties for the
 14 products Plaintiffs purchased. By purchasing the products from Amazon.com, Plaintiffs accepted
 15 and agreed to Amazon’s Conditions of Use (“COUs”).² *See* COUs, dated May 21, 2021, at 1
 16 (providing that by using “Amazon products or services,” an Amazon customer agrees to comply
 17 with the COUs) (Ex. I to Nagamine Decl.); *see also Ekin v. Amazon Servs., LLC*, 84 F. Supp. 3d
 18 1172, 1173 (W.D. Wash. 2014) (explaining that customers “accept the COU every time they make
 19 a purchase on Amazon.com; to make a purchase, customers must click a button next to text that
 20 says ‘by placing your order, you agree to Amazon.com’s *privacy notice* and *conditions of use*,’ the
 21 [emphasized] portions also bearing hyperlinks to the eponymous documents.”). Amazon’s COUs
 22 form a valid and enforceable contract. *See Wiseley v. Amazon.com, Inc.*, 709 F. App’x 862, 863
 23 (9th Cir. 2017) (“The [COUs] … created a valid contract between Amazon and its customers[.]”).

24
 25

² The COUs are expressly referenced in the FAC (¶ 79) and are integral to Plaintiffs’ claims, such that the Court may
 26 consider them with this motion. *See Garner v. Amazon.com, Inc.*, No. C21-0750RSL, 2022 WL 1443680, at *2–3
 (W.D. Wash. May 6, 2022) (considering Amazon online terms and FAQs with a motion to dismiss). The Court may
 also take judicial notice of the COUs. *See id.* at *3; *see also* Amazon’s Request for Judicial Notice, at 1.

1 The Amazon COUs provide in relevant part that:

2 AMAZON MAKES NO REPRESENTATIONS OR WARRANTIES OF ANY
 3 KIND, EXPRESS OR IMPLIED, AS TO THE OPERATION OF THE AMAZON
 4 SERVICES, OR THE INFORMATION, CONTENT, MATERIALS, PRODUCTS
 5 (INCLUDING SOFTWARE) OR OTHER SERVICES INCLUDED ON OR
 6 OTHERWISE MADE AVAILABLE TO YOU THROUGH THE AMAZON
 7 SERVICES, UNLESS OTHERWISE SPECIFIED IN WRITING. . . .

8 TO THE FULL EXTENT PERMISSIBLE BY LAW, AMAZON DISCLAIMS
 9 ALL WARRANTIES, EXPRESS OR IMPLIED, INCLUDING, BUT NOT
 10 LIMITED TO, IMPLIED WARRANTIES OF MERCHANTABILITY AND
 11 FITNESS FOR A PARTICULAR PURPOSE.

12 COUs at 3–4. This waiver is consistent with Wash. Rev. Code § 62A.2-316, which permits parties
 13 to disclaim or modify warranties. And while the Washington Supreme Court held in *Berg v.
 14 Stromme* that disclaimers in consumer automobile purchases must be explicitly negotiated and set
 15 forth with particularity (79 Wash. 2d 184 (1971)), the court subsequently declined to extend those
 16 requirements to transactions analogous to Plaintiffs’ purchases here.

17 In *Travis v. Washington Horse Breeders Ass’n, Inc.*, the Washington Supreme Court
 18 expressed its “reluctan[ce] to extend the [*Berg*] rule in other circumstances” and declined to do so
 19 with respect to auctions, reasoning that auctions do not involve “negotiations such as are typically
 20 found in the purchase of an automobile” and the conditions of sale “were in large, bold type,”
 21 “were legible and easy to read,” and the “final bill of sale was on a single page, easy to read, and
 22 understandable.” 111 Wash. 2d 396, 403 (1988). The court further noted that one purpose of an
 23 auction is “to avoid face-to-face negotiations” and thus serve as “a cost-saving device in which
 24 face-to-face negotiations, except as to price, are not engaged in by the parties.” *Id.* at 403–04.
 25 Plaintiffs’ purchases here exhibit many of the same qualities as the auction in *Travis*. As online
 26 purchases, Plaintiffs’ transactions do not involve face-to-face negotiations. The Amazon COUs,
 27 moreover, set forth the express disclaimer in all capital letters, in a separate section entitled
 28 “DISCLAIMER OF WARRANTIES AND LIMITATION OF LIABILITY”, and in clear and
 29 understandable language. *See* COUs at 3–4. The Court should apply *Travis* to enforce the
 30 disclaimer in Amazon’s COUs and dismiss Plaintiffs’ warranty claim.

MOTION TO DISMISS PLAINTIFFS’ FIRST AMENDED COMPLAINT - 19
CASE NUMBER 2:22-CV-00544-TL

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1 Second, Plaintiffs failed to provide timely notice of their breach of warranty claim.
 2 Washington law requires a buyer, “within a reasonable time after he or she discovers or should
 3 have discovered any breach[,]” to “notify the seller of breach or be barred from any remedy.”
 4 Wash. Rev. Code § 62A.2-607(3)(a). Here, Plaintiffs purchased the medicines in September 2021
 5 and January 2022, but did not send notice to Amazon until April 13, 2022, and filed suit just six
 6 business days later. *See* FAC ¶¶ 7–8, 57. The purpose of the notice requirement is to provide a
 7 seller with a reasonable opportunity to take remedial action. *See Alvarez v. Chevron Corp.*, 656
 8 F.3d 925, 932 (9th Cir. 2011) (purpose of identical California law is “to allow the breaching party
 9 to cure the breach and thereby avoid the necessity of litigating the matter in court”). Plaintiffs
 10 failed to fulfill that requirement and did not afford Amazon a reasonable time to address Plaintiffs’
 11 claims before they filed suit. Washington law thus bars Plaintiffs’ express warranty claim.

12 **2. Plaintiffs fail to state an unjust enrichment claim, or other grounds for
 13 equitable relief, because they have an adequate remedy at law**

14 Plaintiffs seek equitable relief via their unjust enrichment claim (requesting restitution and
 15 disgorgement) and their WCPA claim (unspecified relief). *See* FAC ¶¶ 78, 84–85. Plaintiffs,
 16 however, cannot obtain equitable relief because they have not sufficiently alleged, and cannot
 17 establish, that they lack an adequate remedy at law. *See Sonner v. Premier Nutrition Corp.*, 971
 18 F.3d 834, 844 (9th Cir. 2020) (finding that plaintiff “must establish that she lacks an adequate
 19 remedy at law before securing equitable restitution”); *Clark v. Eddie Bauer LLC*, No. C20-1106-
 20 JCC, 2021 WL 1222521, at *4 (W.D. Wash. Apr. 1, 2021) (“Federal courts are precluded from
 21 awarding equitable relief when an adequate legal remedy exists” (internal alterations omitted)).
 22 At the pleading stage, “the complaint must *first* provide sufficient allegations to explain how a
 23 legal remedy … [is] inadequate.” *Clark*, 2021 WL 1222521, at *4. Plaintiffs must “allege some
 24 facts suggesting that damages are insufficient to make them whole.” *Gibson v. Jaguar Land Rover
 25 N. Am., LLC*, No. CV 20-00769-CJC(GJSx), 2020 WL 5492990, at *4 (C.D. Cal. 2020). Claims
 26 based solely on economic injury are classic examples of claims with an adequate remedy at law—

1 *i.e.*, monetary damages—that preclude awards of equitable relief. *See Clark*, 2021 WL 1222521,
 2 at *4 (dismissing equitable relief claims in false advertising case involving only alleged financial
 3 harm); *Sharma v. Volkswagen AG*, 524 F. Supp. 3d 891, 908 (N.D. Cal. Mar. 9, 2021) (lost money
 4 and value are “exactly the type of injury for which legal remedies are appropriate”).

5 The FAC lacks any explanation as to why potential monetary damages are inadequate or
 6 why Plaintiffs are otherwise entitled to equitable relief. *See* FAC ¶¶ 78 (noting only that Plaintiffs
 7 seek equitable relief under the WCPA), 84–85 (requesting restitution and disgorgement under
 8 unjust enrichment claim). Rather, Plaintiffs’ alleged economic harm is the quintessential injury
 9 for which legal remedies are adequate, and, indeed, Plaintiffs expressly seek money damages for
 10 that alleged harm. *See id.* ¶¶ 77, 94, 104. Plaintiffs do not suggest how an award of restitution or
 11 other equitable relief would provide them additional benefits. *See Hamm v. Mercedes-Benz USA,*
 12 *LLC*, No. 6:16-cv-03370-EJD, 2022 WL 913192, at *5 (C.D. Cal. Mar. 29, 2022).

13 Plaintiffs suggest that they can plead claims for equitable relief because they “cannot
 14 know” if their claims support adequate legal damages. FAC ¶ 86. To the contrary, that is precisely
 15 why Plaintiffs’ claims for equitable relief must be dismissed, *i.e.*, because they “do[] not contain
 16 plausible allegations explaining *why* … legal remedies are inadequate as to past and future harms”
 17 especially where those harms “are financial and … can be cured by the monetary damages, *i.e.*,
 18 *legal relief*, afforded by [other claims].” *Clark*, 2021 WL 1222521, at *4; *see also Sharma*, 524
 19 F. Supp. 3d at 907 (finding that “a prayer for equitable relief [does not] state a claim if the pleading
 20 does not demonstrate the inadequacy of a legal remedy”). Because Plaintiffs are not entitled to
 21 equitable relief, the Court should dismiss: (1) the unjust enrichment claim; and (2) the WCPA
 22 claim to the extent it seeks equitable relief. *See Sonner*, 971 F.3d at 844.

23 **3. Plaintiffs do not allege plausible misrepresentation claims**

24 Plaintiffs have failed to plead intentional and negligent misrepresentation with plausibility,
 25 let alone with Rule 9(b) particularity. The FAC lacks facts to support several elements required
 26 for these claims, including: (1) the existence of a false statement; (2) Amazon’s knowledge of its

1 falsity; (3) Amazon’s intent that Plaintiffs act on the statement; and (4) causation. *See Frias v.*
 2 *Asset Foreclosures Servs., Inc.*, 957 F. Supp. 2d 1264, 1271 (W.D. Wash. 2013) (intentional
 3 misrepresentation); *Seattlehaunts, LLC v. Thomas Family Farm, LLC*, No. C19-1937 JLR, 2020
 4 WL 5500373, at *7 (W.D. Wash. Sept. 11, 2020) (negligent misrepresentation).

5 Preliminarily, as to the first and last elements, Plaintiffs fail to allege a false statement, or
 6 that they relied on such statement to their detriment. As discussed above, Plaintiffs offer no factual
 7 basis upon which the Court may plausibly infer that the non-drowsy medicines cause drowsiness
 8 when taken as directed. *See* Section IV.B, *supra*. Nor do Plaintiffs offer any well-pled facts
 9 concerning their purported reliance on the “representations and warranties” on the products’ labels,
 10 resting instead on conclusory statements and bare recitations of the elements. *See* FAC ¶¶ 8–9
 11 (identical, conclusory allegations), 87–104 (rote recitation of elements). And as also discussed
 12 above, the FAC is devoid of any facts plausibly supporting causation—allegations that Plaintiffs
 13 became “unexpectedly drowsy” at some undisclosed time after they took the medication is simply
 14 not sufficient. *Id.* ¶¶ 8–9; *see also* Section IV.B.3.

15 Plaintiffs also plead no facts to suggest that Amazon had the requisite intent or knowledge.
 16 As to intent, the FAC contains a single conclusory statement that presumes a motive to sell “more
 17 products” at a “price premium.” FAC ¶ 41. As to knowledge, the FAC rests on assumptions and
 18 speculation about what Plaintiffs believe other companies probably do and know about their
 19 products, not on particularized facts about what Amazon actually does, what it knew, or what it
 20 reasonably should have known about DXM. *See id.* Even if Plaintiffs had established that DXM
 21 causes drowsiness (they have not), the FAC does not provide any fact-based allegations to
 22 plausibly infer that the drowsiness effect of DXM was so well-known that Amazon knew or
 23 reasonably should have known about it. To the contrary, the FDA monographs support the
 24 opposite conclusion. *See* 48 Fed. Reg. at 48,589 (finding no data to support a drowsiness warning).

25 Because the FAC lacks plausible allegations to support any the four required elements for
 26 sustaining Plaintiffs’ misrepresentation claims, the Court should dismiss those claims.

1 **D. Plaintiffs Lack Article III Standing for Injunctive Relief**

2 To establish standing to seek injunctive relief, a plaintiff “must demonstrate that he has
 3 suffered or is threatened with a concrete and particularized legal harm, coupled with a sufficient
 4 likelihood that he will again be wronged in a similar way.” *Phillips v. Apple Inc.*, 725 F. App’x
 5 496, 497–98 (9th Cir. 2018) (internal quotation marks omitted). The plaintiff must show that the
 6 threat of future harm is “certainly impending, or there is a substantial risk that the harm will occur.”
 7 *Susan B. Anthony List v. Driehaus*, 573 U.S. 149, 158 (2014) (internal quotation marks omitted).
 8 Where a plaintiff lacks Article III standing, the Court must dismiss her claims under Fed. R. Civ.
 9 P. 12(b)(1). *See McGee v. S-L Snacks Nat'l*, 982 F.3d 700, 705 (9th Cir. 2020).

10 Plaintiffs request undefined “injunctive relief” under the WCPA (FAC ¶ 78) and seek “an
 11 order enjoining [Amazon] from continuing to engage in the wrongful acts and practices alleged
 12 herein” (*id.* p. 21). While the FAC states in conclusory fashion that Plaintiffs might purchase a
 13 Basic Care product labeled as “non-drowsy” sometime in the future, it offers no facts to suggest
 14 any such purchase is real, immediate, or certainly impending. *See Amara*, 2022 WL 3357575, at
 15 *2–3 (finding, in an identical case, that plaintiff lacked standing to seek injunctive relief because
 16 he “offer[ed] only a speculative and conjectural statement that he intends to purchase the Product
 17 at some uncertain future date” and thus failed to allege “any future harm to himself that is real and
 18 immediate and/or certainly pending”). Nor does the FAC suggest that Plaintiffs face an actual,
 19 concrete risk of future deception. Based on Plaintiffs’ allegations, they need only find DXM on a
 20 product’s label to know the product, in their view, might cause drowsiness.

21 Accordingly, Plaintiffs lack standing to seek injunctive relief. *See In re Coca-Cola Prods.*
 22 *Mkg. and Sales Pracs. Litig.*, No. 20-15742, 2021 WL 3878654, at *2 (9th Cir. Aug. 31, 2021)
 23 (plaintiffs lacked standing for injunctive relief because statements they would “‘consider’
 24 purchasing properly labeled Coke are insufficient to show an actual or imminent threat of future
 25 harm”); *Shin v. Umeken USA, Inc.*, 773 F. App’x 373, 375 (9th Cir. 2019) (plaintiff who alleged
 26 products were “worthless” lacks standing for injunctive relief because “a plaintiff certainly will

1 not purchase a worthless product in the future"); *Jackson v. Gen. Mills, Inc.*, No. 18cv2634-LAB
2 (BGS), 2020 WL 5106652, at *5 (S.D. Cal. Aug. 28, 2020) (standing lacking where plaintiff "now
3 knows she can ascertain the amount of cereal she is buying by looking at the label" and thus "has
4 not shown any likelihood she will be deceived in the future"); *Cordes v. Boulder Brands USA,
5 Inc.*, No. CV 18-6534 PSG (JCx), 2018 WL 6714323, at *4-5 (C.D. Cal. Oct. 17, 2018) (no
6 standing where plaintiff "could easily determine" the true nature of the product "before making a
7 future purchase by simply reading the back" of the label).

V. CONCLUSION

9 For the foregoing reasons, Amazon respectfully requests that the Court: (1) grant Amazon's
10 Motion to Dismiss; (2) dismiss all claims alleged in Plaintiffs' FAC with prejudice and without
11 leave to amend; and (3) grant any such other relief as the Court deems just and necessary.

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1 DATED September 7, 2022

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Certification of Conferral

Pursuant to the Court's Standing Order for All Civil Cases, Sections II.D. and II.I., the undersigned counsel for Defendant Amazon.com, Inc. certifies that, via a telephone call on August 31, 2022, counsel for Defendant conferred with counsel for Plaintiffs about the contents of the foregoing Motion to Dismiss Plaintiffs' First Amended Complaint.

DATED September 7, 2022

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